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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,701	03/15/2007	Catharina Philippina Janssen	0702-061238	4395
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THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219			EXAMINER UNDERDAHL, THANE E	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,701	Applicant(s) JANSSEN, CATHARINA PHILIPPINA	
	Examiner THANE UNDERDAHL	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-13,19-28 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) 24,25 and 30-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,19-23,26-28,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

This Office Action is in response to the Applicant's reply received 6/11/10. Claims 1, 7-13, 19-28, 30-37 are pending. Claims 24, 25, 30-35 are withdrawn. Claims 2-6, 14-18, 29, are cancelled. Claims 1, 7, 8, 13, 19-25, 27, 30-35 have been amended. Claims 36 and 37 are new. Claims 1, 7, 19-23, 26-28, 36 and 37 are considered in this Office Action.

Response to Election/Restriction Requirement

Applicant's response, with traverse, to the Restriction/Election requirement filed on 2/26/07 is acknowledged. The applicant elected Group I which includes claims 1, 7, 19-28, 36 and 37.

The Applicant argues that the amended claims are now united under a single special technical feature. The Examiner agrees, however this special technical feature is still known by Vriezema et al. (Angew, Chem. Int. Ed. published online, 2/17/03). This is explained below in the 35 USC § 102 rejection. However claims 27 and 28 are rejoined since these are structurally close to the composition of group I.

The required species elected for a polymer for claims 7-12 is withdrawn due to Applicant's amendments. However the election of species limiting how the hollow particle is modified in suspension remains and the Applicant has elected a glucose solution. Claims 22, 24 and 25 are withdrawn as being directed towards non-elected species. However claim 22 is rejoined since this limitation was found during the course of searching.

Therefore, the Restriction/Election requirement is therefore made FINAL and the elected species and the claims they include will now be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

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of the claimed invention. This claim limits that the enzyme comprises a polypeptide that is linked to the inner side of the hollow particles. The Applicant does not adequately describe how to perform this limitation. Indeed the Applicant teaches in the specification that “[t]he polypeptide preferably is an enzyme” (page 3, lines 14 and 15) and that “[t]he polypeptide could be linked to the inner side of the vesicle by for example a lipophylic tail attached to the enzyme” (page 3, lines 13 and 14). In these two passages the Applicant discloses that the enzymes are linked to the inner side of the particle by a lipophilic tail and not a separate peptide. Therefore they have not provided enough direction to link a peptide to the inner side of the particle and are rejected for a lack of written description on this point.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear to the Examiner the meaning of the word “linked” in the context of claim 8. It is unclear if “link” in this instance means a chemical bond between the enzyme and the particle or simply referring that the enzyme and particle are in close proximity. The common used definition of link can refer to a bond (Merriam-Webster Online, definition 1b) between the particle and the enzyme or some connecting element or factor between (Merriam-Webster Online, definition 2b) the two components such as proximity factor or element of function. In the interest of compact prosecution either definition will read on the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-13, 27, 28 rejected under 35 U.S.C. 102(b) as being anticipated by Vriezema et al. (Angew Chem Int Ed, Published online 2/17/03) in light of support by Lau et al. (Organic Letters, 2000).

These claims are to a device comprising the following:

- Suspension of a plurality of hollow particles with an electrically conductive outer shell;
- The interior of these particles entrap redox-reaction catalyzing enzymes catalyzing an enzymatic conversion of a substrate to liberate electrons;
- The shells of these particles are permeable to the substrate.

The claims further limit that the electrically conductive outer shell comprises **polystyrene-*b*-poly(L-isocyanoalanine(2-thiophe-3-yl-ethyl)amide)** also known as **PS-PIAT**. The thiophene groups of this polymer are polymerized.

These claims include numerous intended results or functional language that define the invention by what it does rather than what it is. MPEP 2114 states that

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"Apparatus claims must be structurally distinguishable from the prior art". Specifically

M.P.E.P. § 2114 state:

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function... [A]pparatus claims cover what a device *is*, not what a device does.

Furthermore M.P.E.P. § 2114 continue to state:

A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim.

In the instant case the permeability and conductivity of the particles is a property of the device and M.P.E.P. § 2112.01 state:

When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent

Therefore art reading on structure of the claimed device will read on the invention. This follows that if art teaching an apparatus with the components in the dependant claims is found then this art also reads on the functional limitations.

Vriezema et al. teach particles made from the block copolymer PS-PIAT (Fig 1 and 2) that encapsulates the redox active enzyme lipase B to keep it linked in close proximity to the inside wall of the particle (pg 775, col 1). **Lipase B (CalB)** inherently oxidizes its substrate, DiFMU octanoate, to liberate their electrons as supported by Lau et al. (Fig 4). Vriezema et al. teaches that these particles are crosslinked by their thiophene side-groups via the chemical oxidant BRP (pg 774, col 1).

Therefore claims 1, 7-13, 27, and 28 are anticipated by the above reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 7-13, 19-23, 26, 27, 28, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vriezema et al. (Angew Chem Int Ed, Published online 2/17/03) as applied to claims 1, 7-13, 27, 28 in the 35 U.S.C. 102(b) rejection above and in further view of Gill et al. (PTO 1449, 4/13/2010, Ref U).

The description and rejection of claims 1, 7-13, 27 and 28 was previously presented above in the USC 102 rejection over Vriezema et al.

While Vriezema et al. teaches that the redox enzyme CalB is encapsulated in PS-PIAT particles they do not teach that the enzyme is glucose oxidase. However Gill et al. teaches that both CalB and glucose oxidase (Gill, page 287, col 1 and Box 5) are common enzymes that are also encapsulated in sol-gels (Gill, Box 2). It would be obvious for one of ordinary skill in the art to simply replace the lipase with glucose oxidase in the particles with Vriezema et al. since it has already been taught that both enzymes are conducive to encapsulation. One of ordinary skill in the art would recognize this as simply applying the known technique of Vriezema et al. to glucose oxidase, when it has already been taught by Gill et al. that both enzymes are successfully encapsulated in sol-gels (KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398

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(2007), pg 12) . Likewise it would be obvious for one of ordinary skill in the art to place these particles in a glucose solution since that is the substrate for glucose oxidase.

One of ordinary skill in the art would predict that glucose would be permeable towards the particle wall since glucose is nearly half the molecular weight of DiFMU octanoate as supported by Sigma Aldrich and Invitrogen.

Also it would be obvious to combine the teachings of Vriezema et al. and Gill et al. and encapsulate the enzymes in the particle of Vriezema et al. and then suspend those particles in the sol-gel of Gill et al. This is because both methods are successful for encapsulating enzymes and retaining their activity. Therefore it would be obvious to combine both methods to encapsulate the enzymes since they are both known for the same purpose (MPEP 2144.06 and (KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007)) pg 13).

Furthermore Gill et al. teach that their sol-gel matrix can be grafted with electronic carriers such as ferrocene, ubiquinone, FAD or NAD derivatives to create “wires” or an electrically conductive matrix for transmitting signals in enzyme sensors (Box 2 and 4).

Therefore claims 1, 7-13, 19-23, 26, 27, 28, 36 and 37 are obvious in view of the above reference(s).

No claims are allowable or free of the art.

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In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651